

## What is ISO 80369

Hospitals and other healthcare facilities depend on a variety of catheters, tubing and syringes to deliver medications and other substances to patients through vascular, enteral, respiratory, epidural and intrathecal delivery systems. These delivery systems frequently employ fittings called luer connectors to link various system components. Unfortunately, because luer connectors are ubiquitous, easy-to-use, and compatible between different delivery systems, end users can inadvertently connect the incorrect systems together. These misconnections can cause medication or other fluids to be delivered through the wrong route, resulting in serious patient injuries and even death. In an effort to reduce the occurrence of these misconnections, the FDA is actively participating internationally to develop and implement standards for the non-interconnectability of small bore medical connectors. A joint working group established by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) leads this effort to develop a series of standards for incompatible connectors. ISO 80369-1 is the first in the series of standards and establishes the applications specified below that will have their own unique connector geometries.

### ISO 80369-1

#### General Requirements

- This standard is already published
- The second edition is currently in ballot
- Comments from this DIS ballot were reviewed partially in March, 2015
- Discussions were held to remove the definition of Small Bore from the standard to prevent it from limiting the connector size
  - The committee agreed to remove the number references
- The committee also discussed the following:
  - Allowing softer materials in sealing surfaces
  - Allowing proprietary connectors to claim compliance to 80369-1
- The standard is expected to be updated to a second edition later in 2016

### ISO 80369-2

#### Respiratory (Breathing Systems)

- The task group now comprises of many global players from the industry
- DIS draft is complete, and the ballot is open
- R1 and R2 designs are changing to address misconnections and dead space
- The standard is expected to release by the end of 2016

### ISO 80369-3

#### Enteral Feeding

- DIS with the proposed connector designs has passed with many favorable votes in the recent ballot
- FDA issued a notification to manufacturers of medical devices with connectors recognizing AAMI's US Provisional Standard for Enteral until the final 80369-3 is published: [www.fda.gov](http://www.fda.gov)
- Efforts to delay the implementation of CA Mandate Bill AB 1847 has passed through multiple steps and is awaiting the Governor's signature. A successful resolution will push the deadline to July, 2016.
- The standard is expected to be released by the end of 2015

### ISO 80369-4

#### Urinary and Urethral

- No updates at this time



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